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| 09/879,382 | 06/11/2001 | David Stoloff | J&J-0102/GYN-082 | 3839 |

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| EXAMINER |
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PHAM, HUNG Q

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| ART UNIT | PAPER NUMBER |
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2168

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/879,382 | Applicant(s) STOLOFF ET AL. | |
| | Examiner HUNG Q. PHAM | Art Unit 2168 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15, 16 and 18-21 is/are rejected.
- 7) ☒ Claim(s) 1 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/05 has been entered.

Amendment to the Claims

The Claims filed on 09/22/05 contains claims 11-14 drawn to an invention nonelected without traverse in the Office Action 03/24/2005. Claims 12-14 have not provided with proper status identifiers. Applicants' representative has been called to confirm these errors, and these claims will be corrected with proper status identifier in the next communication.

Response to Arguments

- Claims 1, 3 and 15 have been amended to comply with 35 U.S.C. § 112, second paragraph. Claim 17 has been canceled. Applicants' arguments with respect to the rejection of claims 1, 3, 15 and 17 have been fully considered. The rejection of claims 3 and 17 under 35 U.S.C. § 112, second paragraph, has been withdrawn. The

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rejection of claims 1 and 15 under 35 U.S.C. § 112, second paragraph, has been maintained as detailed below.

- Applicant's arguments with respect to claims 1-10, 12-16 and 18-21 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: *a computer-readable medium* as recited in claim 8, *an invention submission disclosure form* as recited in claims 6 and 20.

Claim Objections

Claims 1 and 15 are objected to because of the following informalities: *the submissions* at line 9 (in the previous step, only one *submission* participates in the process). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1,

The clause *an indicated unmet need* at line 9 makes the step *selecting* indefinite because (1) it is unclear how “*an unmet need*” is “*indicated*” in the process, (2) it is unclear how the process obtains *an indicated unmet need* for selecting, because in the previous steps, *an unmet need* is not the subject for accepting and categorizing, *a submission indicative of an unmet need* participates in these steps.

The clause *the selected unmet need*, at lines 9 and 10, references to some other items in the claims. It is unclear what item is being referenced.

Regarding claim 15, the clause *an indicated unmet need* at line 7 makes the *whereby* clause indefinite because (1) it is unclear how “*an unmet need*” is “*indicated*” in the system, (2) it is unclear how the system obtains *an indicated unmet need* to be identified because in the system, *an unmet need* is not the subject for accepting and categorizing, *a submission indicative of an unmet need* participates in the system means for accepting and categorizing.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8, 15, 16 and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As set forth in MPEP 2106(IV)(B)(2)(a):

A machine is "a concrete thing, consisting of parts or of certain devices and combinations of devices." *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570 (1863).

If a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product. See, e.g., *Lowry*, 32 F.3d at 1583, 32 USPQ2d at 1034-35; *Warmerdam*, 33 F.3d at 1361-62, 31 USPQ2d at 1760. Office personnel must treat each claim as a whole. The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine or manufacture. Cf. *In re Iwahashi*, 888 F.2d 1370, 1374-75, 12 USPQ2d 1908, 1911-12 (Fed. Cir. 1989), cited with approval in *Alappat*, 33 F.3d at 1544 n.24, 31 USPQ2d at 1558 n.24.

Regarding claims 15, 16 and 18-21, *a system for collecting medical unmet need information* was claimed but the claims contains only software, and do not define the *physical structure of the machine or manufacture in terms of its hardware or hardware and software combination*. Therefore, the claims do not define a statutory system.

Claims 8 direct to *a computer-readable medium bearing computer readable instruction*.

Computer-readable medium as defined in the Specification at page 7, lines 20-21, is *a communication medium*. A communication medium conveys signals such as electrical, electromagnetic, or digital signals. A signal encoded with functional descriptive material does not fall within any of the categories of patentable subject matter. Therefore, claim 8 is not statutory (As set forth in § 101, a claimed signal is clearly not a process under § 101 because it is not a series of steps. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result, and does not fit within the

definition of a machine. A claimed signal is not matter, but a form or energy, and therefore is not a composition of matter or product).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 7-10, 15, 16, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over drugstore.com [drugstore.com – online pharmacy & drugstore, prescriptions filled] in view of Applicant Admitted Prior Art [Background of the Invention, pages 1-3].

Regarding claims 1 and 15, drugstore.com is a computer system implements a method for collecting medical product information, comprising:

providing a web site having information about medical products (drugstore.com, pages 1-2);
accepting on said web site a submission indicative of an unmet need relating to the medical products from a plurality of users (the web site accepts a submission indicative of an unmet need relating to the medical products, e.g., *Does fish oil help lower cholesterol?* as indicated at page 4 by typing the question into the question box at page 3 and right clicking the SUBMIT QUESTION button);

categorizing the submission indicative of the unmet need according to a primary topic (the submission of unmet need could be categorized into particular topic, e.g., ARTHRITIS, OSTEOARTHRITIS... as illustrated at page 4).

The missing of drugstore.com is the step of *selecting an indicated unmet need for development of a medical product related to the selected unmet need where a predetermined number of the submissions have the same primary topic.*

As disclosed in the Background at page 2, lines 6-14, health professionals are often in a position to recognize a need for a product that is not commercially available, recognize the need to improve a marketed product and/or identify a problem with an existing product. The professional may be performing a diagnostic procedure or providing medical or surgical treatment and be in position to recognize improvements

¹ As set forth in MPEP 2111.04:

(A) "adapted to" or "adapted for" clauses;
(B) "wherein" clauses; and
(C) "whereby" clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffar v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "whereby" clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* However, the court noted (quoting *Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "whereby" clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Id.*

Thus, "for development of a medical product related to the selected unmet need" is just the purpose of the step selecting.

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that are needed that could facilitate and/or improve their diagnostic capabilities, offer better medical or surgical treatment options, or increase the efficiency of the procedure while decreasing complications and improving patient outcomes. For example, a physician might notice a 20-30% recurrence rate for pelvic floor prolapse and that a more effective treatment is needed.

As seen, the Background teaches that a threshold could be set for a particular category, and a particular category could be selected if percentage rate of that particular category meets the threshold, and the purpose is to develop a medical product relates to that particular category.

Thus, a threshold as *a predetermined number of the submissions have the same primary topic* could be set and selected for a particular topic as *an indicated unmet need*, and the purpose is for *development of a medical product related to the selected unmet need*.

By combining the teaching of the Background into drugstore.com method, *the information would enable medical companies to offer new and improved products and procedures that would provide the medical professional with superior diagnostic capabilities, and improved surgical treatments options for their patients* as suggested in the Background at page 2, lines 1-5.

Regarding claims 2 and 16, drugstore.com and the Background, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, drugstore.com further discloses *the categorization is done performed by each said plurality of users electronically selecting a category* (page 4).

Regarding claim 4, drugstore.com and the Background, in combination, teach all of the claimed subject matter as discussed above with respect to claim 1, drugstore.com further discloses the step of *providing a gatekeeper such that the gatekeeper filters out input that relates to product complaints* (page 9).

Regarding claims 7 and 21, drugstore.com and the Background, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, drugstore.com further discloses the step of *providing a computer implemented medical products information web site in conjunction with the unmet needs input such that users can input unmet needs while obtaining medical products information* (page 4).

Regarding claim 8, drugstore.com and the Background, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1, and pages 1-10 of drugstore.com are created by a computer process, and these imply *a computer-readable medium bearing computer readable instructions for carrying out the steps recited in claim 1.*

Regarding claim 9, drugstore.com is a web site for collecting medical product information, comprising:

a web site wherein the web site stores information about medical products, information about the medical products being electronically searchable and browseable (pages 1 and 2), and *a computer that hosts the web site is an inherent feature of pages 1 and 2;*

a network connection (WWW) whereby web pages are delivered to a remote computer and input is accepted from the remote computer (any computer that has access to the WWW can retrieve an

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exist web page by inputting an URL), *the network accepting an electronic submission indicative of an unmet need for the medical products* (a plurality of users can input a medical request that are not currently addressed by available medical products in the question form, e.g., *Does fish oil help lower cholesterol?* as indicated at page 4 into SEARCH OUR Q&As box of page 4, or ASK YOUR PHARMACIST at page 3. The question as unmet need is accepted by the website via a SUBMIT QUESTION button).

The missing of drugstore.com is the purpose of the apparatus as claimed: *whereby unmet needs related to the medical products may be² determined for³ the development of a medical product related to the unmet need.*

As disclosed in the Background at page 2, lines 6-14, health professionals are often in a position to recognize a need for a product that is not commercially available, recognize the need to improve a marketed product and/or identify a problem with an existing product. The professional may be performing a diagnostic procedure or providing medical or surgical treatment and be in position to recognize improvements that are needed that could facilitate and/or improve their diagnostic capabilities, offer better medical or surgical treatment options, or increase the efficiency of the procedure while decreasing complications and improving patient outcomes. For example, a physician might notice a 20-30% recurrence rate for pelvic floor prolapse and that a more effective treatment is needed.

² Replacing the clause "*may be identified*" by a positive clause, e.g., "*is identified*", is respectfully suggested in order to particularly point out the claimed invention.

³ "*for development of a medical product related to the categorized submission*" is just the purpose of "*an indicated unmet need*". See Footnote 1.

As seen, the Background teaches that and a particular category could be determined if percentage rate of that particular category meets the threshold, and the purpose is to develop a medical product relates to that particular category.

Thus, a threshold could be set to determine a particular topic as *an indicated unmet need related to the medical products*, and the purpose is for *development of a medical product related to the unmet need*.

By combining the teaching of the Background into drugstore.com method, *the information would enable medical companies to offer new and improved products and procedures that would provide the medical professional with superior diagnostic capabilities, and improved surgical treatments options for their patients* as suggested in the Background at page 2, lines 1-5.

Regarding claim 10, drugstore.com further comprising *a medical products purchasing database whereby a user can purchase medical products in conjunction with the submission of an unmet need submission* (page 2).

Regarding claim 18, drugstore.com further comprising the step of *providing a gatekeeper such that the gatekeeper filters out input that relates to product complaints* (page 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 5, 6, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over drugstore.com [drugstore.com – online pharmacy & drugstore, prescriptions filled], Applicant Admitted Prior Art [Background of the Invention, pages 1-3] as applied to claims 1, 5, 15 and 19 above, and further in view of Wang et al. [USP 6,766,320 B1].

Regarding claim 3, drugstore.com and the Background, in combination, teach all of the claimed subject matter as discussed above with respect to claim 1, drugstore.com further discloses the step of *selecting of the unmet need having a predetermined number of unmet need submissions* (only those submitted questions with the same primary topic, e.g., OSTEoarthritis in *How can I get relief from my osteoarthritis* of page 4, which have already been answered at least once by pharmacists, will be selected for

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processing to make available answer to the user). The missing of drugstore.com and the Background is the step of *filtering the unmet needs submissions*. Wang teaches a search engine to match a question to a set of frequently asked questions stored in a database (Wang, Abstract). Wang further discloses the step of filtering the question (Wang, Col. 8, Lines 40-64). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the drugstore.com technique by including the step of filtering noisy words from an unmet need, e.g., *How can I get relief from my osteoarthritis* of page 4, in order to produce keywords for searching.

Regarding claims 5 and 19, drugstore.com and the Background, in combination, teach all of the claimed subject matter as discussed above with respect to claims 1 and 15, but does not explicitly teach the step of *providing a gatekeeper such that the gatekeeper filters out input that describes a unmet need and a solution to the unmet need*. Wang teaches a search engine to match a question to a set of frequently asked questions stored in a database (Wang, Abstract). Wang further discloses the step of providing a gatekeeper such that the gatekeeper filters out input that describes a unmet need (Wang, Col. 8, Lines 40-64), and a solution to the unmet need (Wang, Col. 11, Line 10-Col. 12, Line 11). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the drugstore.com technique by including the technique of filtering out unmet need and solution as taught by Wang in order to produce key words for searching and matching with the best answer.


Regarding claims 6 and 20, drugstore.com, the Background and Wang, in combination, teach all of the claimed subject matter as discussed above with respect to claims 5 and 19, drugstore.com further discloses *an invention submission disclosure form is transmitted to the user that submitted the unmet need (page 4) and the solution to the unmet need (page 6).*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HUNG Q. PHAM whose telephone number is 571-272-4040. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY A. GAFFIN can be reached on 571-272-4146. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


HUNG Q PHAM
Examiner
Art Unit 2168

February 10, 2006